

Chronology CARDS

JLP41868 30-Nov-2001 Application: N 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date ΑI

Communication Type

Document Type

Document Subtype

Serial / Supp #

12:16:18

22-Aug-1994 "Food and Drug Administration Correspondence

Export

Authorization

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Export: Authorization

26-Jan-1995 Food and Drug Administration Correspondence

Export

Authorization

IND 47,838; GI198745 (5-alpha reductase inhibitor) Export: Authorization

03-Feb-1995 GlaxoSmithKline FAX/E-mail

Export

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Export

23-Feb-1995 Food and Drug Administration Correspondence

Export

Authorization

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Export: Authorization

General Correspondence

28-Feb-1995

GlaxoSmithKline Correspondence

Pre-IND GI198745 (5-alpha reductase inhibitor)
General Correspondence: Request for Comment

CARDS

JLP41868 30-Nov-2001 Application: N 47838; GI198745 (5-alpha reductase inhibitor) Chronology

Date Range: A II

Date

Communication Type

Document Type

Document Subtype

Serial / Supp #

2 12:16:18

24-Apr-1995 GlaxoSmithKline Correspondence

Initial Investigational New Drug Application

CMC Protocol(s) Included Study Reports

Protocol Amendment: New Investigator Protocol Amendment: New Protocol

Investigator Add

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Initial Investigational New Drug Application: CMC, Protocol(s) Included, Study Reports

Protocol Amendment: New Protocol

Protocol Amendment: New Investigator

Serial No.: 0000

28-Apr-1995 Food and Drug Administration Correspondence Acknowledgement

IND # Assigned

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Acknowledgement: IND # Assigned

09-May-1995 GlaxoSmithKline Correspondence

General Correspondence

Clinical Nonclinical

0001

IND 47,838; GI198745 (5-alpha reductase inhibitor)

General Correspondence

Serial No.: 001

CARDS

JLP41868 30-Nov-2001 Application: N 47838; GI198745 (5-alpha reductase inhibitor) Chronology

Date Range:

23-May-1995 Communication Type Document Type

IND 47,838; GI198745 (5-alpha reductase inhibitor) "GlaxoSmithKline Correspondence General Correspondence

Report of Selected Adverse Events

Document Subtype

Serial / Supp #

3 12:16:18

0002

Serial No.: 0002 General Correspondence: Report of Selected Adverse Events

26-May-1995 GlaxoSmithKline Telephone Conversation

General Teleconference

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Record of Telecon

26-May-1995 Food and Drug Administration Telephone

Comment/Information Request

Conversation

IND 47,838; GI198745 (5-alpha reductase inhibitor)

FDA Comment

05-Jun-1995 GlaxoSmithKline Correspondence General Correspondence

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 0003 General Correspondence: Report of Selected Adverse Events

13-Jun-1995 GlaxoSmithKline Correspondence

General Correspondence

IND 47,838; GI198745 (5-alpha reductase inhibitor)

General Correspondence

Serial No.: 004

Report of Selected Adverse Events

0003

Clinical

0004

CARDS Chronology

30-Nov-2001 **Application:** ENI ENI 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All

JLP41868

Communication Type **Document Type** Document Subtype Serial / Supp #

13-Sep-1995 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Protocol Amendment: New Protocol

Investigator Add Investigator Add

0005

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Protocol

Protocol Amendment: New Investigator

Serial No.: 0005

26-Sep-1995 GlaxoSmithKline Correspondence Serial No.: 0006 IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Chemistry Manufacturing and Controls and Controls Information Amendment: Chemistry Manufacturing CMC

10-Oct-1995 GlaxoSmithKline Correspondence Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Other 1572 Change Clinical

0007

9000

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Protocol Amendment: New Investigator

Protocol Amendment: New Investigator Serial No.: 007

13-Oct-1995 GlaxoSmithKline Telephone Conversation General Teleconference Nonclinical

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Record of Telecon

4 12:16:18

CARDS Chronology

30-Nov-2001 **Application:** N 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All

JLP41868

Communication Type

Document Type

Document Subtype

5 12:16:18

Serial / Supp #

03-Nov-1995 25-Oct-1995 18-Oct-1995 18-Oct-1995 16-Oct-1995 GlaxoSmithKline Telephone Conversation GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: CMC Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Clinical General Correspondence: Clinical Serial No.: 0009 Serial No.: 008 Minutes of Meeting: FDA Conference General Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Minutes of Meeting Comment/Information Request General Correspondence General Teleconference CMC FDA Conference Clinical Clinical 0009 8000

Chronology CARDS

47838; GI198745 (5-alpha reductase inhibitor)

JLP41868 30-Nov-2001 Application: N

Date Range: ΑH

Date

Communication Type **Document Type Document Subtype**

Serial / Supp #

6 12:16:18

08-Nov-1995 GlaxoSmithKline Correspondence Serial No.: 010 Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Investigator Add 0010

13-Nov-1995 General Correspondence: CMC GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence CMC

0011

Serial No.: 0011

13-Dec-1995 GlaxoSmithKline Trip Report Topic

Record of Visit to FDA IND 47,838; GI198745 (5-alpha reductase inhibitor)

GlaxoSmithKline Correspondence and Controls Protocol Amendment: New Protocol Information Amendment: Clinical Information Amendment: Nonclinical Information Amendment: Chemistry Manufacturing Protocol Amendment: New Investigator CMC Nonclinical

0012

29-Jan-1996

Protocol Amendment: Change in Protocol Clinical Investigator Add

CARDS

JLP41868 30-Nov-2001 Application: ND 47838; GI198745 (5-alpha reductase inhibitor) Chronology

Date Date Range: A H

Communication Type

Document Subtype

Serial / Supp #

12:16:18

Document Type

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Information Amendment: Chemistry Manufacturing and Controls
Information Amendment: Clinical

Protocol Amendment: New Protocol Information Amendment: Nonclinical

Protocol Amendment: New Investigator

Protocol Amendment: Change in Protocol

Serial No.: 0012

29-Jan-1996 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor)

General Correspondence

Clinical

General Correspondence: Clinical Serial No.: 0013

Comment/Information Request

Clinical Nonclinical

08-Feb-1996

Conversation

Food and Drug Administration Telephone

IND 47,838; GI198745 (5-alpha reductase inhibitor)

FDA Comment

GlaxoSmithKline Telephone Conversation General Teleconference

Clinical

09-Feb-1996

IND 47,838; GI198745 (5-alpha reductase inhibitor)

General Teleconference: Clinical

0013

CARDS

8 12:16:18

30-Nov-2001 **Application:** IND 47838; GI198745 (5-alpha reductase inhibitor) Chronology

JLP41868

Date Date Range: ΑH Communication Type **Document Type** Document Subtype Serial / Supp #

12-Feb-1996 Food and Drug Administration Telephone Conversation Comment/Information Request Clinical Efficacy

IND 47,838; G1198745 (5-alpha reductase inhibitor)
Comment/Information Request: Clinical

22-Feb-1996 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 014 Protocol Amendment: New Investigator Protocol Amendment: New Investigator Investigator Add

0014

22-Feb-1996 General Teleconference: Electronic Submission IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Telephone Conversation General Teleconference Other

29-Feb-1996 GlaxoSmithKline Correspondence Information Amendment: Nonclinical Study Reports Nonclinical 0015

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Information Amendment: Nonclinical
Serial No.: 015

18-Mar-1996 GlaxoSmithKline Correspondence General Correspondence Clinical 0016

CARDS

JLP41868 30-Nov-2001 Application: H 47838; GI198745 (5-alpha reductase inhibitor) Chronology

Date Range: <u>A</u>

Date Communication Type **Document Type Document Subtype**

Serial / Supp #

9 12:16:18

 General Correspondence: Clinical "IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 0016

22-Mar-1996 GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Other 1572 Change

Investigator Add

0017

Protocol Amendment: New Investigator Serial No.: 0017 IND 47,838; GI198745 (5-alpha reductase inhibitor)

02-Apr-1996 Food and Drug Administration Telephone Comment/Information Request

Nonclinical

Conversation

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Comment/Information Request: Nonclinical

15-Apr-1996 GlaxoSmithKline Telephone Conversation

Response to FDA Request/Comment

Nonclinical Clinical

IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment: Nonclinical

19-Apr-1996 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Nonclinical Serial No.: 0018

General Correspondence

Nonclinical

0018

30-Nov-2001 **Application:** Date 24-Apr-1996 24-Apr-1996 23-Apr-1996 Date Range: JLP41868 19-Jun-1996 ΑII ND Communication Type GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Comment/Information Request: Clinical Food and Drug Administration Correspondence Serial No.: 020 Protocol Amendment: New Investigator Protocol Amendment: New Protocol IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0019 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) 47838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request Protocol Amendment: New Investigator Protocol Amendment: New Protocol Protocol Amendment: New Investigator Protocol Amendment: New Investigator Document Type Chronology Other 1572 Change Clinical Investigator Add **Document Subtype** Other 1572 Change Investigator Add Serial / Supp # 9 0021 0020 12:16:18

Serial No.: 021

Date Range: Date 30-Nov-2001 **Application:** 14-Aug-1996 29-Jul-1996 24-Jun-1996 JLP41868 Α N Annual Report Serial No.: 022 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence Communication Type GlaxoSmithKline Correspondence Response to FDA Request/Comment: Nonclinical Serial No.: 0023 IND 47,838; GI198745 5-Alpha Reductase Inhibitor 47838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: New Investigator Protocol Amendment: Change in Protocol Response to FDA Request/Comment Annual Report Document Type Chronology CMC Nonclinical Clinical Investigator Add Foreign Marketing Developments **Document Subtype** Serial / Supp # 0022 0024 0023 12:16:18

Protocol Amendment: New Protocol Protocol Amendment: New Investigator Protocol Amendment: Change in Protocol Serial No.: 0024

IND 47,838; GI198745 (5-alpha reductase inhibitor)

JLP41868

Date Range: Date 30-Nov-2001
Application: 02-Oct-1996 02-Oct-1996 11-Sep-1996 29-Aug-1996 IND GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence Communication Type GlaxoSmithKline Correspondence GlaxoSmithKline Correspondence General Correspondence General Correspondence Serial No.: 027 Serial No.: 026 Protocol Amendment: Change in Protocol Serial No.: 0025 Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) 47838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator General Correspondence General Correspondence Protocol Amendment: Change in Protocol **Document Type** Chronology Clinical Other Investigator Add Other 1572 Change Document Subtype Serial / Supp # 0025 0027 0026 12:16:18

09-Oct-1996

Conversation

Food and Drug Administration Telephone

Comment/Information Request

JLP41868 31-Oct-1996 23-Oct-1996 15-Oct-1996 15-Oct-1996 Date Range: Application: 30-Nov-2001 ΑII IND Information Request "IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence Food and Drug Administration Correspondence GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Meeting Request GlaxoSmithKline Telephone Conversation Protocol Amendment: New Investigator Protocol Amendment: Change in Protocol Communication Type Serial No.: 0029 IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 028 IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details 47838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator General Correspondence General Teleconference General Correspondence Document Type Chronology Clinical Meeting Request Investigator Add **Document Subtype** Meeting Agenda or Details Meeting Agenda or Details Serial / Supp # 0029 0028 12:16:18

IND 47,838; GI198745 (5-alpha reductase inhibitor)

General Correspondence: Meeting Agenda or Details

JLP41868

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26-Nov-1996		18-Nov-1996	15-Nov-1996		06-Nov-1996	04-Nov-1996	Date Range: Date	14 30-Nov-2001 Application:
Food and Drug Administration Telephone Conversation	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical, Meeting Agenda or Details Serial No.: 0032	GlaxoSmithKline Correspondence	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 0031	IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Clinical	Food and Drug Administration Correspondence	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: CMC Serial No.: 0030	All Communication Type	IND 47838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request	r Details	General Correspondence	General Correspondence		Comment/Information Request	General Correspondence	Document Type	Chronology itor)
Clinical Electronic Format		Clinical Meeting Agenda or Details	Clinical		Clinical	CMC	Document Subtype	
		0032	0031			0030	Serial / Supp #	12:16:18

JLP41868

30-Nov-2001 **Application:** 30-Jan-1997 28-Jan-1997 18-Dec-1996 Date Range: 18-Dec-1996 All N GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details Communication Type GlaxoSmithKline Telephone Conversation GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0033 IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 035 Serial No.: 0034 General Correspondence: Clinical Comment/Information Request: Clinical, Electronic Format Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor) 47838; GI198745 (5-alpha reductase inhibitor) General Teleconference Protocol Amendment: New Investigator General Correspondence General Correspondence **Document Type** Chronology CMC Other 1572 Change Clinical Meeting Agenda or Details **Document Subtype** Serial / Supp # 0035 0034 0033 12:16:18

Record of Telecon

20-Mar-1997		05-Mar-1997		04-Mar-1997		10-Feb-1997	Date Range: Date	16 30-Nov-2001 Application:	JLP41868
GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 039	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 038	GlaxoSmithKline Correspondence	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Serial No.: 0037	GlaxoSmithKline Correspondence	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: New Investigator Serial No.: 0036	GlaxoSmithKline Correspondence	All Communication Type	IND 47838; GI198745 (5-alpha reductase inhibitor)	
Protocol Amendment: New Investigator		General Correspondence		Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator		Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Document Type	Chronology bitor)	CARDS
Investigator Add				Clinical Other 1572 Change	Investigator Add		Document Subtype		
0039		0038		0037		0036	Serial / Supp #	12:16:18	

Application: 30-Nov-2001 JLP41868 D 47838; GI198745 (5-alpha reductase inhibitor) Chronology 12:16:18

Date Range: Date Communication Type Document Type **Document Subtype** Serial / Supp #

23-May-1997 GlaxoSmithKline Correspondence General Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence

0040

02-Jun-1997 GlaxoSmithKline Correspondence Serial No.: 040 Information Amendment: Chemistry Manufacturing Protocol Amendment: New Investigator Protocol Amendment: New Protocol Investigator Add

0041

Protocol Amendment: Change in Protocol Protocol Amendment: New Protocol IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol and Controls CMC Clinical

Protocol Amendment: New Investigator Information Amendment: Chemistry Manufacturing and Controls

03-Jun-1997 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Other 1572 Change Investigator Add

0042

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator
Serial No.: 0042

Date Range: Date 30-Nov-2001 **Application:** 04-Jun-1997 JLP41868 ΑII IND "GlaxoSmithKline Correspondence Communication Type 47838; GI198745 (5-alpha reductase inhibitor) General Correspondence Document Type Chronology **Document Subtype** Serial / Supp # 0043 12:16:18

IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence
Serial No.: 043

09-Jun-1997 GlaxoSmithKline Telephone Conversation Record of Telecon IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference

11-Jun-1997 GlaxoSmithKline Correspondence Annual Report

IND 47,838; GI198745 (5-alpha reductase inhibitor) Annual Report Serial No.: 044

02-Jul-1997 GlaxoSmithKline Correspondence Information Amendment: Clinical

IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Clinical Serial No.:045

0044

Foreign Marketing Developments

13-Aug-1997	07-Aug-1997	01-Aug-1997	29-Jul-1997	22-Jul-1997	Date Range: Date	JLP41868 19 30-Nov-2001 Application:
. GlaxoSmithKline Correspondence	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 048	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 047	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 046	All Communication Type	IND 47838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Protocol Protocol Amendment: New Investigator Amendment: Other	Protocol Amendment: New Investigator	General Correspondence	General Correspondence	Protocol Amendment: New Investigator	Document Type	CARDS Chronology itor)
Investigator Add Transfer of Obligations to Contract	Other 1572 Change	Other	CMC	Investigator Add	Document Subtype St	
0049	0048		0047	0046	Serial/Supp#	12:16:18

JLP41868

30-Nov-2001 **Application:** IND

47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range: ΑI

Date

Communication Type

Document Type

Document Subtype

Serial / Supp #

12:16:18

Research Organization

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Protocol Amendment: New Protocol Protocol Amendment: New Investigator

Amendment: Other, Transfer of Obligations to Contract Research Organization

Serial No.: 0049

15-Aug-1997 GlaxoSmithKline Correspondence

Information Amendment: Chemistry Manufacturing

0050

and Controls

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Information Amendment: Chemistry Manufacturing and Controls

Serial No.: 050

Comment/Information Request

CMC

19-Aug-1997 Food and Drug Administration Correspondence

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Comment/Information Request: CMC

20-Aug-1997 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 051 Minutes of Meeting

Minutes of Meeting

End of Phase II Meeting

0051

28-Aug-1997 Food and Drug Administration Correspondence

Comment/Information Request

Comment/Information Request IND 47,838; GI198745 (5-alpha reductase inhibitor)

30-Nov-2001 **Application:** Date 08-Sep-1997 28-Aug-1997 Date Range: JLP41868 11-Sep-1997 10-Sep-1997 ΑII Z Communication Type GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 052 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence Food and Drug Administration Correspondence General Correspondence Minutes of Meeting: End of Phase II Meeting IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 053 Protocol Amendment: New Investigator 47838; GI198745 (5-alpha reductase inhibitor) General Correspondence Protocol Amendment: New Investigator Protocol Amendment: Change in Protocol Protocol Amendment: New Protocol Minutes of Meeting Protocol Amendment: New Investigator **Document Type** Chronology **Document Subtype** End of Phase II Meeting Clinical Investigator Add Other 1572 Change Clinical Serial / Supp # 0053 0052 0054 12:16:18

Protocol Amendment: New Protocol Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator

IND 47,838; GI198745 (5-alpha reductase inhibitor)

30-Nov-2001 **Application:** Date 22-Sep-1997 19-Sep-1997 11-Sep-1997 Date Range: JLP41868 ΑII Z "Serial No.: 0054 GlaxoSmithKline Telephone Conversation GlaxoSmithKline Correspondence General Teleconference GlaxoSmithKline Telephone Conversation General Teleconference IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) Communication Type 47838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator General Teleconference General Teleconference **Document Type** Chronology Investigator Add Other 1572 Change **Document Subtype** Serial / Supp # 0055 12:16:18

25-Sep-1997

GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol

Protocol Amendment: Change in Protocol

Clinical

0056

Protocol Amendment: New Investigator Serial No.: 0055

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 56

09-Oct-1997 01-Oct-1997 Date Range: 02-Oct-1997 Application: 10-Oct-1997 30-Nov-2001 JLP41868 ΑII B "GlaxoSmithKline Telephone Conversation GlaxoSmithKline Correspondence GlaxoSmithKline Correspondence GlaxoSmithKline Correspondence Communication Type Serial No.: 058 Serial No.: 0057 Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Draft Protocol IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Chemistry Manufacturing and Controls, CMC Information Amendment: Nonclinical, Study Reports IND 47,838; GI198745 (5-alpha reductase inhibitor) 47838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Protocol Amendment: Change in Protocol and Controls Protocol Amendment: New Investigator General Teleconference Information Amendment: Nonclinical Information Amendment: Chemistry Manufacturing Document Type Chronology Investigator Add Clinical Other 1572 Change **Draft Protocol** Study Reports Investigator Add **Document Subtype** Serial / Supp # 0058 0057 12:16:18

IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol

Other 1572 Change

Serial No.: 0059

Protocol Amendment: New Investigator

Date 27-Oct-1997 24-Oct-1997 21-Oct-1997 Date Range: Application: 30-Nov-2001 JLP41868 16-Oct-1997 ΑII IND Communication Type GlaxoSmithKline Correspondence GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 060 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Clinical Food and Drug Administration Telephone Protocol Amendment: Change in Protocol Annual Report: Changes to Investigator's Brochure Conversation Serial No.: 061 General Correspondence Information Amendment: Chemistry Manufacturing and Controls 47838; GI198745 (5-alpha reductase inhibitor) and Controls Comment/Information Request General Correspondence Protocol Amendment: Change in Protocol Annual Report Document Type Information Amendment: Chemistry Manufacturing Chronology Clinical Changes to Investigator's Brochure Clinical Study Information Clinical **Document Subtype** Statistical Serial / Supp # 0060 0062 0061 12:16:18

Serial No.: 062

01-Dec-1997	11-Nov-1997	03-Nov-1997	31-Oct-1997	Date Range: Date	JLP41868 25 30-Nov-2001 Application:
Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0065	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 064	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0063	All Communication Type	IND 47838; GI198745 (5-alpha reductase inhibitor)
General Teleconference	Protocol Amendment: New Investigator	Protocol Amendment: Change in Protocol	Protocol Amendment: New Investigator	Document Type	CARDS Chronology bitor)
Meeting Request	Investigator Add Other 1572 Change	Clinical	Investigator Add Other 1572 Change	Document Subtype	
	0065	0064	0063	Serial / Supp #	12:16:18

JLP41868

0068	Clinical CMC	Response to FDA Request/Comment	GlaxoSmithKline Correspondence	08-Dec-1997
			IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0066	
0066	Investigator Add Other 1572 Change	Protocol Amendment: New Investigator	GlaxoSmithKline Correspondence	05-Dec-1997
0067	СМС	Response to FDA Request/Comment	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comments Serial No.: 067	05-Dec-1997
	CMC	Comment/Information Request	Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Other	03-Dec-1997
			IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment: Statistical	
Serial/Supp#	Document Subtype Statistical	Document Type Response to FDA Request/Comment	All Communication Type 'GlaxoSmithKline Telephone Conversation	Date Range: Date 02-Dec-1997
12:16:18		Chronology bitor)	IND 47838; GI198745 (5-alpha reductase inhibitor)	26 30-Nov-2001 Application:

IND 47,838; GI198745 (5-alpha reductase inhibitor)

30-Nov-2001 **Application:** Date Date Range: JLP41868 08-Jan-1998 15-Dec-1997 15-Dec-1997 22-Jan-1998 ΑII N "General Correspondence Serial No.: 068 Communication Type GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline FAX/E-mail GlaxoSmithKline Correspondence Food and Drug Administration Telephone Response to FDA Request/Comment: Statistical IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0069 IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Other IND 47,838; GI198745 (5-alpha reductase inhibitor) Conversation 47838; GI198745 (5-alpha reductase inhibitor) General Memorandum Response to FDA Request/Comment Protocol Amendment: New Investigator General Teleconference Document Type Protocol Amendment: Change in Protocol Chronology Other **Document Subtype** Other 1572 Change Meeting Agenda or Details Statistical Clinical Investigator Add Serial / Supp # 0069 0070 12:16:18

Protocol Amendment: Change in Protocol

Serial No.: 070

18-Feb-1998	11-Feb-1998	04-Feb-1998		29-Jan-1998	Date Range: Date	28 30-Nov-2001 Application:	JLP41868
GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Clinical Request for waivers for non-US Studies Serial No.: 075	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 073	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Statistical Serial No.: 072	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0071	GlaxoSmithKline Correspondence	All Communication Type	IND 47838; GI198745 (5-alpha reductase inhibitor)	
Information Amendment: Clinical	General Correspondence	General Correspondence		Protocol Amendment: New Investigator	Document Type	Chronology pitor)	CARDS
Other	Clinical Draft Protocol	Statistical		Investigator Add Other 1572 Change	Document Subtype		
0075	0073	0072		0071	Serial / Supp#	12:16:18	

JLP41868

27-Mar-1998	06-Mar-1998		26-Feb-1998	18-Feb-1998	Date Range: Date	29 30-Nov-2001 Application:
GlaxoSmithKline Correspondence	GlaxoSmithKline Correspondence Information Amand Controls IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Chemistry Manufacturing and Controls, CMC Serial No.: 077	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Serial No.: 0076	GlaxoSmithKline Correspondence	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 074	All Communication Type	IND 47838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator	Information Amendment: Chemistry Manufacturing and Controls		Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	General Correspondence	Document Type	Chronology itor)
Investigator Add Other 1572 Change	CMC		Clinical Investigator Add Other 1572 Change	Statistical	Document Subtype	
0078	0077		0076	0074	Serial / Supp#	12:16:18

IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0078

30-Nov-2001 **Application:**

JLP41868

IND

47838; GI198745 (5-alpha reductase inhibitor)

Chronology

12:16:18

Date Range: All

Communication Type

Date

Document Type

Document Subtype

Serial / Supp #

02-Apr-1998 Food and Drug Administration Telephone

Comment/Information Request

Clinical

Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor)

Comment/Information Request: Clinical

03-Apr-1998 Food and Drug Administration Telephone Conversation

Comment/Information Request

Statistical

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Comment/Information Request

GlaxoSmithKline Telephone Conversation

General Teleconference

CMC

09-Apr-1998

General Teleconference: CMC IND 47,838; GI198745 (5-alpha reductase inhibitor)

17-Apr-1998 Food and Drug Administration Correspondence

Comment/Information Request

Clinical

IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Clinical

23-Apr-1998 GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor)

General Teleconference

CMC

30-Nov-2001 Application: Date Date Range: 27-Apr-1998 28-Apr-1998 JLP41868 11-May-1998 30-Apr-1998 ΙΝ̈́ ΑII "General Teleconference: CMC GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 0079 Protocol Amendment: New Investigator GlaxoSmithKline Correspondence Communication Type GlaxoSmithKline Correspondence Serial No.: 080 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 081 47838; GI198745 (5-alpha reductase inhibitor) General Correspondence Protocol Amendment: Change in Protocol Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Document Type Chronology Clinical Other 1572 Change **Document Subtype** Clinical Clinical Investigator Add Serial / Supp # 0079 080 0081 0082 12:16:18

General Correspondence

IND 47,838; GI198745 (5-alpha reductase inhibitor)

30-Nov-2001 Application:

JLP41868

IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range: ΑII

12-May-1998 "Food and Drug Administration Telephone Communication Type

Document Type

Comment/Information Request

Clinical Document Subtype

Serial / Supp #

12:16:18

Protocol

Conversation

IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Clinical, Protocol

28-May-1998 Food and Drug Administration Correspondence

Comment/Information Request

Statistical Clinical

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Comment/Information Request: Clinical, Statistical

29-May-1998 GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add Other 1572 Change

Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 0083

29-May-1998 GlaxoSmithKline Telephone Conversation

Response to FDA Request/Comment

Clinical Protocol

IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment: Clinical

0083

JLP41868

23-Jun-1998	22-Jun-1998	19-Jun-1998		09-Jun-1998	Date Range: Date	33 30-Nov-2001 Application:
. GlaxoSmithKline Correspondence	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Serial No.: 086	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 085	IND 47,838; GI198745 (5-alpha reductase inhibitor) Annual Report Serial No.: 084	GlaxoSmithKline Correspondence	All Communication Type	IND 47838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator	Protocol Amendment: New Protocol	General Correspondence		Annual Report	Document Type	Chronology Ibitor)
Investigator Add Other 1572 Change		Clinical		Adverse Event Summary Clinical Study Information CMC Outstanding Regulatory Business	Document Subtype	
0087	0086	0085		0084	Serial / Supp #	12:16:18

IND 47,838; GI198745 (5-alpha reductase inhibitor)

30-Nov-2001 **Application:** ND 47838; GI198745 (5-alpha reductase inhibitor) Chronology

Date Range: ΑII

JLP41868

Communication Type

"Protocol Amendment: New Investigator Serial No.: 0087

Document Type

Document Subtype

Serial / Supp #

12:16:18

8800

01-Jul-1998 GlaxoSmithKline Correspondence and Controls Information Amendment: Chemistry Manufacturing CMC

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 088 Information Amendment: Chemistry Manufacturing and Controls

09-Jul-1998 GlaxoSmithKline Correspondence Protocol Amendment: Change in Protocol Protocol Amendment: New Protocol

0089

Protocol Amendment: New Investigator Investigator Add Clinical

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Protocol Amendment: New Protocol

Serial No.: 0089

GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Clinical

0090

Protocol Amendment: Change in Protocol Serial No.: 0090

31-Jul-1998

03-Aug-1998

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add
Other 1572 Change

0091

35 30-Nov-2001 Date 31-Aug-1998 Date Range: Application: JLP41868 06-Oct-1998 14-Sep-1998 10-Aug-1998 Z Communication Type Protocol Amendment: New Investigator Serial No.: 0091 GlaxoSmithKline Correspondence Serial No.: 092 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0093 IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence Serial No.: 0094 Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol 47838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: New Investigator Protocol Amendment: New Investigator Protocol Amendment: New Investigator Protocol Amendment: Change in Protocol **Document Type** Chronology Investigator Add Other 1572 Change Other 1572 Change Clinical **Document Subtype** Investigator Add Serial / Supp # 0092 0093 0094 0095 12:16:18

30-Nov-2001 **Application:** Date Range: JLP41868 A∐ ND 47838; GI198745 (5-alpha reductase inhibitor) Chronology 12:16:18

Communication Type Document Type

Protocol Amendment: New Protocol Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor) Investigator Add

Document Subtype

Serial / Supp #

Serial No.: 0095

13-Oct-1998 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Investigator Add Other 1572 Change

0096

Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 0096

28-Oct-1998 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Investigator Add Other 1572 Change

Protocol Amendment: New Investigator Serial No.: 0097

IND 47,838; GI198745 (5-alpha reductase inhibitor)

06-Nov-1998

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add Other 1572 Change

8600

Protocol Amendment: New Investigator Serial No.: 0098

0097

17-Dec-1998 Date Range: Application: 30-Nov-2001 JLP41868 22-Dec-1998 18-Nov-1998 10-Nov-1998 23-Dec-1998 IND IND 47,838; GI198745 (5-alpha reductase inhibitor) Communication Type Protocol Amendment: New Investigator Serial No.: 0101 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Serial No.: 0100 GlaxoSmithKline Correspondence Serial No.: 099 Protocol Amendment: Change in Protocol GlaxoSmithKline Correspondence GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0102 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) 47838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Protocol Amendment: New Investigator Document Type Protocol Amendment: New Investigator Chronology Other 1572 Change Other 1572 Change Clinical Other 1572 Change Investigator Add Document Subtype Investigator Add Investigator Add Serial / Supp # 0100 0099 0103 0102 0101 12:16:18

30-Nov-2001 **Application:** IND

JLP41868

47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range: ΑII

Communication Type

Document Type

Document Subtype

Serial / Supp #

12:16:18

"Protocol Amendment: New Investigator

Serial No.: 103

13-Jan-1999 GlaxoSmithKline Correspondence

Information Amendment: Chemistry Manufacturing

and Controls

CMC

0104

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Information Amendment: Chemistry Manufacturing and Controls, CMC

Serial No.: 104

15-Jan-1999 IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Other 1572 Change Investigator Add

0105

Protocol Amendment: New Investigator

Serial No.: 0105

GlaxoSmithKline Correspondence Protocol Amendment: New Investigator

Investigator Add Other 1572 Change

0106

02-Feb-1999

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Protocol Amendment: New Investigator Serial No.: 0106

18-Feb-1999 GlaxoSmithKline Correspondence

Protocol Amendment: New Protocol

Protocol Amendment: New Investigator

Investigator Add

0107

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Regulatory Affairs

JLP41868

30-Nov-2001 **Application:** IND

47838; GI198745 (5-alpha reductase inhibitor)

Chronology

12:16:18

Date Range: ΑII

Date

Document Type

Document Subtype

Serial / Supp #

Communication Type

Protocol Amendment: New Protocol Protocol Amendment: New Investigator

Serial No.: 0107

03-Mar-1999 GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Other 1572 Change Investigator Add

0108

Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 0108

04-Mar-1999 GlaxoSmithKline Correspondence

Information Amendment: Chemistry Manufacturing

CMC

0109

and Controls

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Information Amendment: Chemistry Manufacturing and Controls, CMC

Serial No.: 109

08-Mar-1999 GlaxoSmithKline Correspondence

Protocol Amendment: New Protocol

Protocol Amendment: New Investigator

Investigator Add

0110

Protocol Amendment: New Protocol Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor)

12-Mar-1999 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor)

Protocol Amendment: Change in Protocol

Clinical

0111

27-Apr-1999	06-Apr-1999	02-Apr-1999	19-Mar-1999	Date Range: Date	JLP41868 40 30-Nov-2001 Application:
GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0115	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 114	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Amendment: Other, Change in Medical Monitor Serial No.: 113	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0112	All Communication Type "Protocol Amendment: Change in Protocol Serial No.: 111	IND 47838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator	Protocol Amendment: New Investigator	Amendment: Other	Protocol Amendment: New Investigator	Document Type	CARDS Chronology Ditor)
Other 1572 Change	Other 1572 Change	Change in Medical Monitor	Investigator Add Other 1572 Change	Document Subtype	
0115	0114	0113	0112	Serial / Supp #	12:16:18

09-Jun-1999	21-May-1999	19-May-1999	29-Apr-1999	Date Range:	JLP41868 41 30-Nov-2001 Application:
GlaxoSmithKline Correspondence	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0117	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Statistical Serial No.: 0116	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: CMC	All Communication Type	IND 47838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Protocol Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Protocol Amendment: New Investigator	General Correspondence	College Folescomercies	Document Type	CARDS Chronology pitor)
Clinical Investigator Add	Other 1572 Change	Statistical		Document Subtype	
0119	0117	0116		Serial / Supp #	12:16:18

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Protocol
Protocol Amendment: Change in Protocol
Protocol Amendment: New Investigator
Serial No.: 0119

30-Nov-2001
Application: 09-Jun-1999 Date Range: JLP41868 24-Jun-1999 22-Jun-1999 10-Jun-1999 ND GlaxoSmithKline Correspondence GlaxoSmithKline Correspondence
IND 47,838; GI198745 (5-alpha reductase inhibitor) Injection, 0.0111 mg GI198745X per mL
General Correspondence: CMC -Phase I IV Solution Communication Type GlaxoSmithKline Correspondence General Teleconference: Status Update Food and Drug Administration Telephone Serial No.: 0120 Annual Report IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) Conversation Serial No.: 0118 Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor) 47838; GI198745 (5-alpha reductase inhibitor) Annual Report General Teleconference Protocol Amendment: New Investigator Document Type Chronology CMC Investigator Add Other 1572 Change Investigational Plan
Outstanding Regulatory Business Adverse Event Summary Clinical Study Information Status Update Document Subtype 8100 Serial / Supp # 0120 0121 12:16:18

15-Jul-1999	06-Jul-1999		02-111-1999	24-Jun-1999	Date Range: Date	JLP41868 43 30-Nov-2001 Application:
Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Other	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0124	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: New Investigator Serial No.: 0123	GlaxoSmithKline Correspondence	GlaxoSmithKline Correspondence IND 47,838; GI198745 Soft Gelatin Capsules, 0.5 mg General Correspondence: CMC - Specification and Test Methods Serial No.: 0122	All Communication Type Serial No.: 0121	IND 47838; GI198745 (5-alpha reductase inhibitor)
Comment/Information Request	Protocol Amendment: New Investigator	Protocol Amendment: New Investigator	Protocol Amendment: New Protocol	General Correspondence g est Methods	Document Type	CARDS Chronology bitor)
Other	Other 1572 Change	Investigator Add		CMC	Document Subtype	
	0124		0123	0122	Serial / Supp #	12:16:18

17-Aug-1999	30-Jul-1999	22-Jul-1999	21-Jul-1999	20-Jul-1999	Date Range: Date	JLP41868 44 30-Nov-2001 Application:
GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0129	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0128	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 0127	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 0126	GlaxoSmithKline Correspondence IND 47,838; G1198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0125	All Communication Type	IND 47838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator	Protocol Amendment: New Investigator	General Correspondence	Protocol Amendment: Change in Protocol	Protocol Amendment: New Investigator	Document Type	CARDS Chronology pitor)
Other 1572 Change	Other 1572 Change	Clinical	Clinical	Other 1572 Change	Document Subtype	
0129	0128	0127	0126	0125	Serial / Supp #	12:16:18

JLP41868

45 30-Nov-2001 01-Sep-1999 09-Sep-1999 01-Sep-1999 Date Range: Application: 10-Sep-1999 ND GlaxoSmithKline Correspondence Food and Drug Administration Telephone GlaxoSmithKline Telephone Conversation Communication Type IND 53,551; GI262570X General Correspondence: Meeting Agenda or Details GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Clinical, Safety General Correspondence: Meeting Agenda or Details Serial No.: 0130 Information Amendment: Chemistry Manufacturing and Controls, CMC IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) Conversation Serial No.: 0072 Serial No.: 0131 47838; GI198745 (5-alpha reductase inhibitor) General Teleconference and Controls General Teleconference General Correspondence Information Amendment: Chemistry Manufacturing Document Type Chronology Clinical Safety CMC Status Update Meeting Agenda or Details Document Subtype Serial / Supp # 0130 0131 12:16:18

General Teleconference: Status Update

JLP41868		Regulatory Allairs CARDS		
46 30-Nov-2001 Application:	IND 47838; GI198745 (5-alpha reductase inhibitor)	Chronology itor)		12:16:18
Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
24-Sep-1999	GlaxoSmithKline Correspondence I5-Da IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0132 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0021 10-Day ADR Report: Initial	15-Day ADR Report	Initial	0132
26-Oct-1999	GlaxoSmithKline Correspondence	Improper Conduct by an Investigator		0133
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Improper Conduct by an Investigator Serial No.: 0133			
28-Oct-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Statistical Serial No.: 0134	General Correspondence	Statistical	0134
28-Oct-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Minutes of Meeting Serial No.: 0135	Minutes of Meeting	FDA Conference	0135
28-Oct-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor)	15-Day ADR Report	Initial	0136

30-Nov-2001 01-Nov-1999 Date Range: Application: JLP41868 02-Nov-1999 22-Nov-1999 10-Nov-1999 ND IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia "Serial No.: 0136 Protocol Amendment: New Investigator Serial No.: 0137 GlaxoSmithKline Correspondence GlaxoSmithKline Correspondence Protocol Amendment: New Protocol Serial No.: 0023 Communication Type IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 0139 General Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence Serial No.: 0138 Information Amendment: Clinical, Statistical IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) 10-Day ADR Report: Initial 47838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol General Correspondence Information Amendment: Clinical Protocol Amendment: New Investigator Protocol Amendment: New Protocol Document Type Chronology CARDS **Document Subtype** Clinical Statistical Clinical Investigator Add Serial / Supp # 0137 0138 0140 0139 12:16:18

Serial No.: 0140

	15-Dec-1999	10-Dec-1999	08-Dec-1999	03-Dec-1999	Date Range: Date	JLP41868 48 30-Nov-2001 Application:
IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0144	GlaxoSmithKline Correspondence	GlaxoSmithKline Correspondence 15-Da IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0143 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0024 10-Day ADR Report: Follow-up	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0142	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 0141	All Communication Type	IND 47838; GI198745 (5-alpha reductase inhibitor)
	Protocol Amendment: New Investigator	15-Day ADR Report Alopecia	Protocol Amendment: New Investigator	Protocol Amendment: Change in Protocol	Document Type	CARDS Chronology oitor)
	Investigator Add Other 1572 Change	Follow-up	Investigator Add	Clinical	Document Subtype	
	0144	0143	0142	0141	Serial / Supp #	12:16:18

49 30-Nov-2001 Date JLP41868 05-Jan-2000 05-Jan-2000 28-Dec-1999 22-Dec-1999 Date Range: Application: N All Communication Type Conversation Serial No.: 0145 GlaxoSmithKline Correspondence Serial No.: 0146 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia IND 47,838; GI198745 (5-alpha reductase inhibitor) Food and Drug Administration Telephone General Correspondence: Statistical IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Other IND 47,838; GI198745 (5-alpha reductase inhibitor) Conversation Food and Drug Administration Telephone Serial No.: 0025 IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence Comment/Information Request: Statistical 10-Day ADR Report: Initial 47838; GI198745 (5-alpha reductase inhibitor) General Teleconference General Correspondence Comment/Information Request Document Type 15-Day ADR Report Chronology Other Initial **Document Subtype** Statistical Statistical Serial / Supp # 0146 0145 12:16:18

06-Jan-2000

Food and Drug Administration Telephone

General Teleconference

Other

Conversation

General Teleconference: Other

IND 47,838; GI198745 (5-alpha reductase inhibitor)

30-Nov-2001 **Application:** Date Range:

JLP41868

N

47838; GI198745 (5-alpha reductase inhibitor)

Chronology

ΑII Communication Type

Date

Document Type

Serial / Supp #

12:16:18

Document Subtype

10-Jan-2000

Food and Drug Administration Telephone Conversation

Comment/Information Request

Other

11-Jan-2000

GlaxoSmithKline Correspondence

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Comment/Information Request: Other

Protocol Amendment: New Investigator

Other 1572 Change Investigator Add

0147

Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 0147

GlaxoSmithKline Telephone Conversation

Response to FDA Request/Comment

Safety

11-Jan-2000

IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment: Safety

17-Jan-2000 GlaxoSmithKline FAX/E-mail

Response to FDA Request/Comment

Other

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Response to FDA Request/Comment: Other

19-Jan-2000 GlaxoSmithKline Correspondence

15-Day ADR Report

Follow-up

0148

30-Nov-2001 **Application:** 02-Feb-2000 Date Range: JLP41868 24-Feb-2000 02-Feb-2000 ΑII ND "IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence Serial No.: 0148 Serial No.: 0027 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Communication Type GlaxoSmithKline Correspondence GlaxoSmithKline Correspondence Serial No.: 0150 Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0028 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0149 10-Day ADR Report: Follow-up 10-Day ADR Report: Initial 47838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Document Type Protocol Amendment: New Investigator 15-Day ADR Report Chronology Investigator Add Other 1572 Change Initial Other 1572 Change Investigator Add Document Subtype Serial / Supp # 0150 0151 0149 12:16:18

Serial No.: 0151

Protocol Amendment: New Investigator

JLP41868 52 30-Nov-2001 Application: Date Range: Date 14-Mar-2000	8; GI198745 (5-alpha reductase inhibit 1 Type c Correspondence 98745 (5-alpha reductase inhibitor) ner, Letter of Authorization e Correspondence 98745 (5-alpha reductase inhibitor) ment: Change in Protocol ment: Change in Protocol ment: New Investigator	CARDS Chronology itor) Document Type Amendment: Other Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	으
Date 14-Mar-2000	Communication Type SlaxoSmithKline Correspondence ND 47,838; GI198745 (5-alpha reductase inhibitor) Amendment: Other, Letter of Authorization Serial No.: 0153	Document Type Amendment: Other	
14-Mar-2000		Protocol Amendment: Change in Protocol Amendment: New Investig	rotocol zator
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Serial No.: 0152		
30-Mar-2000	GlaxoSmithKline Correspondence IS-Da IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0154 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0030 10-Day ADR Report: Follow-up	15-Day ADR Report	
14-Apr-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0155	Protocol Amendment: New Investigator	gator
21-Apr-2000	Food and Drug Administration Telephone Conversation	General Teleconference	

05-May-2000 Date 03-May-2000 Date Range: Application: 30-Nov-2001 JLP41868 N All "IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Other GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0031 Serial No.: 0156 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence Communication Type IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0157 10-Day ADR Report: Initial 47838; GI198745 (5-alpha reductase inhibitor) Document Type 15-Day ADR Report 15-Day ADR Report Chronology Initial **Document Subtype** Follow-up Serial / Supp # 0157 0156 12:16:18

19-May-2000 GlaxoSmithKline Correspondence Serial No.: 0032 10-Day ADR Report: Follow-up Protocol Amendment: New Investigator Other 1572 Change Investigator Add

23-May-2000

GlaxoSmithKline FAX/E-mail

General Memorandum

Safety

Serial No.: 0158

Protocol Amendment: New Investigator

IND 47,838; GI198745 (5-alpha reductase inhibitor)

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Date 23-May-2000 Date Range: Application: 30-Nov-2001 JLP41868 09-Jun-2000 24-May-2000 15-Jun-2000 ΑII Z GlaxoSmithKline Telephone Conversation Communication Type Serial No.: 0159 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia 7-Day Safety Report GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0160 IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0034 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence 10-Day ADR Report: Initial Serial No.: 0033 [0-Day ADR Report: Follow-up 47838; GI198745 (5-alpha reductase inhibitor) **Document Type** 7-Day Safety Report Protocol Amendment: New Investigator 15-Day ADR Report 15-Day ADR Report Chronology Safety Initial Document Subtype Other 1572 Change Follow-up Serial / Supp # 0159 0160 0161 12:16:18

Serial No.: 0161

13-Jul-2000	13-Jul-2000	27-Jun-2000	23-Jun-2000	Date Range: Date	JLP41868 55 30-Nov-2001 Application:
GlaxoSmithKline Correspondence IS-Da IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0165 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0036 10-Day ADR Report: Follow-up	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0164	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Annual Report Serial No.: 0163	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0162 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0035 10-Day ADR Report: Follow-up	All Communication Type	i i IND 47838; GI198745 (5-alpha reductase inhibitor)
15-Day ADR Report	Protocol Amendment: New Investigator	Annual Report	15-Day ADR Report	Document Type	CARDS Chronology itor)
Follow-up	Investigator Add Other 1572 Change	Clinical Study Information Investigational Plan	Follow-up	Document Subtype	
0165	0164	0163	0162	Serial / Supp #	12:16:18

16-Aug-2000	08-Aug-2000	18-Jul-2000	17-Jul-2000	Date Range: Date	JLP41868 56 30-Nov-2001 Application:
GlaxoSmithKline Correspondence	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 0167	GlaxoSmithKline Correspondence I5-Da IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0166 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0037 10-Day ADR Report: Initial	GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) 7-Day Safety Report	All Communication Type	IND 47838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: New Investigator	Protocol Amendment: Change in Protocol	15-Day ADR Report Alopecia	7-Day Safety Report	Document Type	CARDS Chronology bitor)
Investigator Add Other 1572 Change	Clinical	Initial	Safety	Document Subtype	
0168	0167	0166		Serial / Supp #	12:16:18

IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0168

24-Aug-2000	24-Aug-2000	22-Aug-2000	21-Aug-2000	Date Range: Date 17-Aug-2000	JLP41868 57 30-Nov-2001 Application:
GlaxoSmithKline Correspondence	GlaxoSmithKline Correspondence 15-Da IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0171 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0040 10-Day ADR Report: Initial	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0170 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0039 10-Day ADR Report: Initial	GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) 7-Day Safety Report	All Communication Type Docu GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0169 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0038 10-Day ADR Report: Follow-up	IND 47838; GI198745 (5-alpha reductase inhibitor)
Information Amendment: Clinical	15-Day ADR Report	15-Day ADR Report	7-Day Safety Report	Document Type 15-Day ADR Report Alopecia	CARDS Chronology itor)
Other	Initial	Initial	Safety	Document Subtype Follow-up	
0172	0171	0170		Serial / Supp # 0169	12:16:18

22-Sep-2000		20-Sep-2000	19-Sep-2000	28-Aug-2000	Date Range: Date	JLP41868 58 30-Nov-2001 Application:	1
GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Request Serial No.: 0176	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0175	GlaxoSmithKline Correspondence	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 0174	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: CMC Serial No.: 0173	All Communication Type IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Clinical, Other Serial No.: 0172	IND 47838; GI198745 (5-alpha reductase inhibitor)	
General Correspondence		Protocol Amendment: New Investigator	General Correspondence	General Correspondence	Document Type General Correspondence	CARDS Chronology bitor)	Tregament / minute
Meeting Request		Investigator Add Other 1572 Change	Clinical	CMC	Document Subtype Draft Protocol		
0176		0175 ·	0174	0173	Serial / Supp #	12:16:18	

JLP41868

06-Oct-2000	03-Oct-2000	27-Sep-2000	26-Sep-2000	26-Sep-2000	Date Range: Date	59 30-Nov-2001 Application:
Food and Drug Administration Correspondence	Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Meeting Request	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: CMC Meeting Request Serial No.: 0178	Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Status Update	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Serial No.: 0177	All Communication Type	IND 47838; GI198745 (5-alpha reductase inhibitor)
General Correspondence	General Teleconference	General Correspondence	General Teleconference	Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Document Type	Chronology bitor)
Meeting Agenda or Details	Meeting Request	CMC	Status Update	Investigator Add	Document Subtype	
		0178		0177	Serial / Supp #	12:16:18

30-Nov-2001
Application:

JLP41868

ND

47838; GI198745 (5-alpha reductase inhibitor)

Chronology

12:16:18

Date Date Range:

All

Communication Type

Document Type

Document Subtype

Serial / Supp #

IND 47,838; G1198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details

13-Oct-2000 GlaxoSmithKline Telephone Conversation

General Teleconference

Meeting Agenda or Details

IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference: CMC, Meeting Agenda or Details

17-Oct-2000 Food and Drug Administration Correspondence

Comment/Information Request

Clinical Protocol

IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request

Food and Drug Administration Correspondence

17-Oct-2000

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Comment/Information Request

19-Oct-2000 GlaxoSmithKline Correspondence

Comment/Information Request

Clinical

Protocol Amendment: New Investigator

Investigator Add Other 1572 Change

0179

Date Range: Application: JLP41868 27-Oct-2000 23-Oct-2000 30-Nov-2001 30-Oct-2000 All Z "IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0179 Protocol Amendment: New Investigator GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Food and Drug Administration FAX/E-mail Communication Type GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Memorandum: Meeting Agenda or Details IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Correspondence: Meeting Agenda or Details
Pre-NDA Meeting Information Package Comment/Information Request: CMC Serial No.: 0180 47838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request General Memorandum Document Type General Correspondence Protocol Amendment: Change in Protocol Chronology Clinical Meeting Agenda or Details Nonclinical Protocol Meeting Agenda or Details Document Subtype Clinical Serial / Supp # 0180 0181 12:16:18

Serial No.: 0181

Protocol Amendment: Change in Protocol

30-Nov-2001
Application: 06-Nov-2000 Date 02-Nov-2000 Date Range: JLP41868 09-Nov-2000 07-Nov-2000 A Ħ GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0182 Communication Type GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0041 Serial No.: 0183 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia GlaxoSmithKline Telephone Conversation Serial No.: 0184 Protocol Amendment: Change in Protocol Information Amendment: Clinical, Statistical 10-Day ADR Report: Initial 47838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol General Teleconference Document Type Information Amendment: Clinical 15-Day ADR Report Chronology Initial CMC Clinical Document Subtype Meeting Agenda or Details Statistical Serial / Supp # 0184 0183 0182 12:16:18

IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: CMC

0187	Follow-up	15-Day ADR Report Alopecia	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0187 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia	30-Nov-2000
	Clinical	Comment/Information Request	Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Clinical Comment on Pre-NDA Meeting Package	27-Nov-2000
0186	CMC	Response to FDA Request/Comment	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment: CMC Serial No.: 0186	17-Nov-2000
0185	Investigator Add Other 1572 Change	Protocol Amendment: New Investigator	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0185	17-Nov-2000
			IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details	
Serial / Supp #	Document Subtype Meeting Agenda or Details	Document Type General Correspondence	All Communication Type Food and Drug Administration Correspondence	Date Range: Date 09-Nov-2000
12:16:18		CARDS Chronology oitor)	IND 47838; GI198745 (5-alpha reductase inhibitor)	JLP41868 63 30-Nov-2001 Application:

JLP41868

64 30-Nov-2001 Application: Date 05-Dec-2000 05-Dec-2000 01-Dec-2000 06-Dec-2000 Date Range: ΑI IND "Serial No.: 0042 GlaxoSmithKline Trip Report 10-Day ADR Report: Follow-up Communication Type GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details Food and Drug Administration Correspondence Serial No.: 0188 Protocol Amendment: Change in Protocol GlaxoSmithKline Correspondence Type: Pre-NDA Meeting Serial No.: 0189 IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) 47838; GI198745 (5-alpha reductase inhibitor) Type General Correspondence Protocol Amendment: Change in Protocol Document Type General Correspondence Chronology Meeting Agenda or Details Pre-NDA Meeting Clinical Document Subtype Meeting Agenda or Details Serial / Supp # 0189 0188 12:16:18

08-Dec-2000

GlaxoSmithKline Correspondence

General Correspondence

Nonclinical

0190

30-Nov-2001 **Application:** 15-Dec-2000 Date Range: JLP41868 02-Jan-2001 18-Dec-2000 14-Dec-2000 <u>A</u> IND 'IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence Serial No.: 0191 Protocol Amendment: New Investigator GlaxoSmithKline Correspondence Serial No.: 0190 General Correspondence: Nonclinical GlaxoSmithKline Correspondence GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 47,838; GI198745 (5-alpha reductase inhibitor) Communication Type Serial No.: 0193 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0192 Response to FDA Request/Comment: Clinical, Draft Protocol IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0043 10-Day ADR Report: Follow-up IND 47,838; GI198745 (5-alpha reductase inhibitor) 47838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment Protocol Amendment: New Investigator Document Type 15-Day ADR Report 15-Day ADR Report Chronology Clinical Initial Follow-up Other 1572 Change Document Subtype **Draft Protocol** Serial / Supp # 0191 0192 0194 0193 12:16:18

Serial No.: 0194

IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia

30-Nov-2001 **Application:** Date Date Range: JLP41868 ΑII DND "Serial No.: 0044 Communication Type 47838; GI198745 (5-alpha reductase inhibitor) **Document Type** Chronology **Document Subtype** Serial / Supp # 12:16:18

03-Jan-2001 Food and Drug Administration Correspondence Comment/Information Request: Statistical IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request Statistical

10-Day ADR Report: Initial

08-Jan-2001 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0195 10-Day ADR Report: Follow-up Serial No.: 0045 15-Day ADR Report Follow-up

0195

09-Jan-2001 GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) 7-Day Safety Report Safety

7-Day Safety Report

10-Jan-2001 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0196 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0046 15-Day ADR Report Initial

0196

10-Day ADR Report: Initial

08-Feb-2001	02-Feb-2001	12-Jan-2001		11-Jan-2001	Date Range: Date	JLP41868 67 30-Nov-2001 Application:
GlaxoSmithKline Correspondence	GlaxoSmithKline Correspondence Response to FDA Request/Com IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment: CMC Teleconference Held on November 9, 2000 Serial No.: 0199	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0198 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0048 10-Day ADR Report: Follow-up	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0197	GlaxoSmithKline Correspondence	All Communication Type	IND 47838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Response to FDA Request/Comment erence Held on November 9, 2000	15-Day ADR Repoπ Alopecia		Protocol Amendment: New Investigator	Document Type	CARDS Chronology pitor)
Clinical Investigator Add Other 1572 Change	CMC	Follow-up		Investigator Add Other 1572 Change	Document Subtype	
0200	0199	0198		0197	Serial / Supp#	12:16:18

IND 47,838; GI198745 (5-alpha reductase inhibitor)
Protocol Amendment: Change in Protocol
Protocol Amendment: New Investigator

30-Nov-2001 **Application:** Date Range: JLP41868 ΑII Z 47838; GI198745 (5-alpha reductase inhibitor) Chronology 12:16:18

Date "Serial No.: 0200 Communication Type Document Type Document Subtype

Serial / Supp #

08-Feb-2001 GlaxoSmithKline Telephone Conversation General Teleconference CMC

IND 47,838; GI198745 (5-alpha reductase inhibitor)
General Teleconference: CMC

2001
GlaxoSmithKline Correspondence
IND 47,838; GI198745 (5-alpha reductase inhibitor)
Serial No.: 0201

19-Feb-2001 Serial No.: 0201 10-Day ADR Report: Initial Serial No.: 0049 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Initial

0201

05-Mar-2001 Serial No.: 0202 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0050 15-Day ADR Report Follow-up

0202

09-Mar-2001 Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Other 1572 Change 0203

Serial No.: 0203

10-Day ADR Report: Follow-up

JLP41868	30-Nov-2001 Application: IND	Date Range: All Date Commun	30-Mar-2001 GlaxoSmithKlin IND 47,838; GII Information Am Serial No.: 0204	09-Apr-2001 GlaxoSmithKlin IND 47,838; GII Protocol Amend: Serial No.: 0205	08-May-2001 GlaxoSmithKlind IND 47,838; GI1 Protocol Amendd Serial No.: 0206	07-Jun-2001 GlaxoSmithKlin IND 47,838; GII Protocol Amend Serial No.: 0207	21-Im-2001 GlaxoSmithKline Correspondence
	47838; GI198745 (5-alpha reductase inhibitor)	Communication Type	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Clinical Serial No.: 0204	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0205	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0206	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0207	
CARDS	Chronology itor)	Document Type	Information Amendment: Clinical	Protocol Amendment: New Investigator	Protocol Amendment: New Investigator	Protocol Amendment: New Investigator	
		Document Subtype	Other	Other 1572 Change	Other 1572 Change	Other 1572 Change	11
	12:16:18	Serial / Supp#	0204	0205	0206	0207	0208

30-Nov-2001 **Application:** Date Range: 06-Aug-2001 27-Jul-2001 25-Jul-2001 JLP41868 18-Jul-2001 ΑII IND Communication Type GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Annual Report IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0051 Serial No.: 0209 GlaxoSmithKline Correspondence Serial No.: 0208 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0052 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia IND 47,838; GI198745 (5-alpha reductase inhibitor) 15-Day ADR Report: Follow-up Serial No.: 0211 Serial No.: 0210 Protocol Amendment: New Investigator 15-Day ADR Report: Initial 47838; GI198745 (5-alpha reductase inhibitor) Document Type Protocol Amendment: New Investigator 15-Day ADR Report 15-Day ADR Report 15-Day ADR Report Chronology Initial Follow-up Other 1572 Change Document Subtype Follow-up Serial / Supp # 0210 0209 0211 0212 12:16:18

Serial No.: 0212

20-Sep-2001	06-Sep-2001	05-Sep-2001	31-Aug-2001	Date Range: Date	JLP41868 71 30-Nov-2001 Application:
GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor)	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0215	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0214 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0055 15-Day ADR Report: Initial	GlaxoSmithKline Correspondence IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0054 IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0213 General Correspondence: Clinical	All Communication Type Docu IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0053 15-Day ADR Report: Follow-up	IND 47838; GI198745 (5-alpha reductase inhibitor)
15-Day ADR Report	Protocol Amendment: New Investigator	15-Day ADR Report lopecia	General Correspondence lopecia	Document Type lopecia	CARDS Chronology tor)
Follow-up	Investigator Add Other 1572 Change	Initial	Clinical	Document Subtype	
0216	0215	0214	0213	Serial / Supp #	12:16:18

72 30-Nov-2001 Date Range: Date 07-Nov-2001 08-Oct-2001 Application: 30-Nov-2001 JLP41868 AII ND "Serial No.: 0216 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) NAS; Not Product Specific GlaxoSmithKline Correspondence GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0217 General Correspondence: Other Serial No.: 0218 Protocol Amendment: New Investigator Serial No.: 0056 Communication Type Protocol Amendment: New Investigator 15-Day ADR Report: Follow-up 47838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator General Correspondence Protocol Amendment: New Investigator Document Type Chronology Other 1572 Change Other 1572 Change Document Subtype Serial / Supp # 0219 0218 0217 12:16:18

EXHIBIT 8B Document Chronology/Due Diligence Logs for NDA 21-319 Express Mail Label No.: EL395889738US

CARDS

12:17:58

30-Nov-2001 21319; Dutasteride Soft-Gelatin Capsules Chronology

Application: NDX

JLP41868

22-Sep-2000 Date Range: "Food and Drug Administration FAX/E-mail Communication Type General Memorandum Document Type Status Update Document Subtype Serial / Supp #

NDA 21-319; Dutasteride Soft-Gelatin Capsules General Memorandum: User Fee ID #

06-Oct-2000 Food and Drug Administration Correspondence General Correspondence Meeting Agenda or Details

NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: Meeting Agenda or Details

19-Dec-2000 GlaxoSmithKline Correspondence User Fee Establishment With Clinical Data

NDA 21-319; Dutasteride Soft-Gelatin Capsules
User Fee ID Number 4030: Establishment With Clinical Data

19-Dec-2000 Conversation Food and Drug Administration Telephone NDA 21-319; Dutasteride Soft-Gelatin Capsules General Teleconference

Status Update

General Teleconference: Status Update

19-Dec-2000 GlaxoSmithKline Telephone Conversation General Teleconference Request Status Update

NDA 21-319; Dutasteride Soft-Gelatin Capsules General Teleconference: Request Status Update

CARDS

JLP41868 30-Nov-2001 **Application:** NDA 21319; Dutasteride Soft-Gelatin Capsules

Chronology

2 12:17:58

Serial / Supp #

21-Dec-2000 21-Dec-2000 Date Range: All GlaxoSmithKline Correspondence Communication Type GlaxoSmithKline Correspondence General Correspondence: CMC Field Copy NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence Original Submission General Correspondence Document Type Clinical CMC Field Copy DMF CMC Field Copy **Document Subtype** Patent Information Establishment Nonclinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules **Original Submission**

02-Jan-2001 NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Desk Copies Conversation Food and Drug Administration Telephone

Comment/Information Request

Other

CARDS Chronology

3 12:17:58

JLP41868 30-Nov-2001 Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Date Range: AII Communication Type **Document Type Document Subtype** Serial / Supp #

03-Jan-2001 NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Desk Copies GlaxoSmithKline Correspondence Response to FDA Request/Comment Other

26-Jan-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment Clinical Statistical

NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment

01-Feb-2001 GlaxoSmithKline Telephone Conversation Response to FDA Request/Comment CMC

01-Feb-2001 GlaxoSmithKline Telephone Conversation Response to FDA Request/Comment

Response to FDA Request/Comment: CMC NDA 21-319; Dutasteride Soft-Gelatin Capsules

NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC

CMC

JLP41868 30-Nov-2001 Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

> Chronology CARDS

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Date Range: Date 08-Feb-2001 08-Feb-2001 06-Feb-2001 02-Feb-2001 "GlaxoSmithKline Telephone Conversation NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC Communication Type GlaxoSmithKline Telephone Conversation NDA 21-319; Dutasteride Soft-Gelatin Capsules Conversation Comment/Information Request NDA 21-319; Dutasteride Soft-Gelatin Capsules Conversation Food and Drug Administration Telephone Comment/Information Request Food and Drug Administration Telephone Comment/Information Request Response to FDA Request/Comment General Teleconference Comment/Information Request Document Type Clinical Statistical CMC Clinical CMC CMC Nonclinical Electronic Format **Document Subtype** Meeting Agenda or Details Serial / Supp #

Chronology

JLP41868 30-Nov-2001 Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: Α

Date

Communication Type

"General Teleconference: Meeting Agenda or Details

Document Type

Document Subtype

Serial / Supp #

5 12:17:58

13-Feb-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment

Clinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request for Information on Clinical Investigators

21-Feb-2001

GlaxoSmithKline Correspondence

General Correspondence

Meeting Agenda or Details

NDA 21-319; Dutasteride Soft-Gelatin Capsules

General Correspondence: Meeting Agenda or Details, Other

01-Mar-2001 GlaxoSmithKline Correspondence

Response to FDA Request/Comment

Clinical CMC

Nonclinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment

20-Apr-2001 GlaxoSmithKline Correspondence

120-Day Safety Update

NDA 21-319; Dutasteride Soft-Gelatin Capsules

Safety

JLP41868 30-Nov-2001 Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

CARDS Chronology

6 12:17:58

08-May-2001 09-May-2001 08-May-2001 07-May-2001 Date Range: ΑII "120-Day Safety Update: Safety GlaxoSmithKline Telephone Conversation NDA 21-319; Dutasteride Soft-Gelatin Capsules General Memorandum: CMC Communication Type NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC GlaxoSmithKline Correspondence Food and Drug Administration Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Nonclinical GlaxoSmithKline FAX/E-mail Minutes of Meeting NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence Response to FDA Request/Comment **Document Type** Minutes of Meeting General Memorandum CMC CMC FDA Conference Nonclinical **Document Subtype** Serial / Supp #

15-May-2001

GlaxoSmithKline Correspondence

General Correspondence

CMC

CARDS Chronology

JLP41868 30-Nov-2001 Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Date Range: ΑH

Communication Type

Document Type

Document Subtype

Serial / Supp #

12:17:58

12-Jun-2001 12-Jun-2001 NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC GlaxoSmithKline Telephone Conversation Food and Drug Administration Correspondence General Teleconference: CMC Minutes of Meeting: FDA Conference NDA 21-319; Dutasteride Soft-Gelatin Capsules NDA 21-319; Dutasteride Soft-Gelatin Capsules Minutes of Meeting Comment/Information Request General Teleconference CMC CMC FDA Conference

14-Jun-2001 GlaxoSmithKline Telephone Conversation

General Teleconference

CMC

NDA 21-319; Dutasteride Soft-Gelatin Capsules General Teleconference: CMC

15-Jun-2001 GlaxoSmithKline Correspondence

Amendment to Pending Application

Clinical Nonclinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules

Chronology

JLP41868 30-Nov-2001 Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: ΑII

Date

Communication Type

Document Type

Document Subtype

Serial / Supp #

"Amendment to Pending Application: Clinical, Nonclinical

27-Jun-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment

CMC

NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC-Site Change for the Blister Pack Foil Lidding

General Correspondence: CMC Meeting Minutes for June 14, 2001 NDA 21-319; Dutasteride Soft-Gelatin Capsules 27-Jun-2001

GlaxoSmithKline Correspondence

General Correspondence

CMC

27-Jun-2001 GlaxoSmithKline Correspondence General Correspondence CMC Field Copy

NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC Field Copy

27-Jun-2001 GlaxoSmithKline Correspondence General Correspondence

CMC

NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC - 36-Month Stability Update

27-Jun-2001 GlaxoSmithKline Correspondence

User Fee

Response to Reconciliation Request

8 12:17:58

CARDS Chronology

JLP41868 30-Nov-2001 Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: ΑIJ

Communication Type

Document Type

Document Subtype

Serial / Supp #

12:17:58

FDA Invoice 975586

User Fee: Response to Reconciliation Request

NDA 19-958; CUTIVATE® (fluticasone propionate cream) Cream, 0.05% NDA 21-254; ADVAIR™ HFA (fluticasone propionate/salmeterol) Inhalation Aerosol 44mcg/21mcg, 110mcg/21mcg, 220mcg/21mcg NDA 21-319; Dutasteride Soft-Gelatin Capsules

CMC Field Copy

General Correspondence

NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC Field Copy

27-Jun-2001

GlaxoSmithKline Correspondence

GlaxoSmithKline Correspondence Response to FDA Request/Comment Other

NDA 21-319; Dutasteride Soft-Gelatin Capsules

02-Jul-2001

Response to FDA Request/Comment: Other, Financial Disclosure

02-Jul-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment

Nonclinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules

Response to FDA Request/Comment: Nonclinical

GlaxoSmithKline Correspondence

09-Jul-2001

Amendment to Pending Application

Labeling

JLP41868

Application: 30-Nov-2001 NDA

21319; Dutasteride Soft-Gelatin Capsules

Chronology

Serial / Supp #

Date Range: ΑII

Communication Type

"NDA 21-319; Dutasteride Soft-Gelatin Capsules

Amendment to Pending Application: Tradename; Labeling

Document Type

Document Subtype

13-Jul-2001 GlaxoSmithKline Correspondence

Response to FDA Request/Comment

Labeling

NDA 21-319; Dutastende Soft-Gelatin Capsules Response to FDA Request/Comment: Labeling

16-Jul-2001 GlaxoSmithKline Telephone Conversation

General Teleconference

CMC

NDA 21-319; Dutasteride Soft-Gelatin Capsules General Teleconference: CMC

16-Jul-2001 GlaxoSmithKline Correspondence

Minutes of Meeting

FDA Conference

NDA 21-319; Dutasteride Soft-Gelatin Capsules

Minutes of Meeting

20-Jul-2001 GlaxoSmithKline Correspondence

Amendment to Pending Application

Labeling Nonclinical Clinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules

Amendment to Pending Application: Labeling, Nonclinical, Human Pharmacokinetics

12:17:58

Chronology

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Application:	NDA	21319; Dutastende Sott-Gelatin Capsules
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30-Nov-2001

JLP41868

Date Range: All Communication Type **Document Type Document Subtype** Serial / Supp #

20-Jul-2001 NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Statistical GlaxoSmithKline Correspondence Response to FDA Request/Comment Statistical

26-Jul-2001 NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Nonclinical GlaxoSmithKline Correspondence Response to FDA Request/Comment Nonclinical

30-Jul-2001 GlaxoSmithKline Telephone Conversation Response to FDA Request/Comment Nonclinical

Response to FDA Request/Comment NDA 21-319; Dutasteride Soft-Gelatin Capsules

30-Jul-2001 Food and Drug Administration Correspondence Minutes of Meeting FDA Conference

02-Aug-2001 Food and Drug Administration FAX/E-mail NDA 21-319; Dutasteride Soft-Gelatin Capsules Minutes of Meeting Comment/Information Request Nonclinical

JLP41868

30-Nov-2001 Application: Date Date Range: ΑII NDA Communication Type 21319; Dutasteride Soft-Gelatin Capsules Document Type Chronology

"NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Nonclinical

07-Aug-2001 GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment Nonclinical

Response to FDA Request/Comment: Nonclinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Statistical

14-Aug-2001

GlaxoSmithKline Correspondence

20-Aug-2001 Food and Drug Administration Correspondence Comment/Information Request: CMC NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request

NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment

23-Aug-2001

GlaxoSmithKline Correspondence

Document Subtype

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Statistical

Response to FDA Request/Comment

CMC

Efficacy Clinical

Response to FDA Request/Comment

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JLP41868

Date Range: Date 30-Nov-2001 **Application:** 07-Sep-2001 06-Sep-2001 04-Sep-2001 07-Sep-2001 10-Sep-2001 NDA GlaxoSmithKline Correspondence Communication Type GlaxoSmithKline Correspondence GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Statistical GlaxoSmithKline Telephone Conversation Response to FDA Request/Comment: Nonclinical NDA 21-319; Dutasteride Soft-Gelatin Capsules Food and Drug Administration Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC - August 27, 2001 NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: Clinical, Statistical 21319; Dutasteride Soft-Gelatin Capsules User Fee Invoice General Correspondence Response to FDA Request/Comment Response to FDA Request/Comment Response to FDA Request/Comment Document Type Chronology Clinical Statistical CMC Nonclinical Product Statistical Document Subtype

NDA 21-319; Dutasteride Soft-Gelatin Capsules

30-Nov-2001 Application: JLP41868 NDA

21319; Dutasteride Soft-Gelatin Capsules

Chronology

Date Range: All

Date "User Fee Invoice Communication Type

Document Subtype

Serial / Supp #

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Document Type

13-Sep-2001 GlaxoSmithKline Telephone Conversation

Clinical

Statistical

Response to FDA Request/Comment

NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Clinical, Statistical

19-Sep-2001 GlaxoSmithKline Correspondence

Response to FDA Request/Comment

Clinical Statistical

NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Clinical, Statistical

GlaxoSmithKline Telephone Conversation

General Teleconference

CMC

25-Sep-2001

General Teleconference: CMC NDA 21-319; Dutasteride Soft-Gelatin Capsules

26-Sep-2001 GlaxoSmithKline Telephone Conversation

General Teleconference

CMC

NDA 21-319; Dutasteride Soft-Gelatin Capsules General Teleconference: CMC

Chronology

JLP41868

Date Range:
Date 15 30-Nov-2001 Application: ΑII NDA Communication Type 21319; Dutasteride Soft-Gelatin Capsules Document Type Document Subtype

27-Sep-2001 GlaxoSmithKline Correspondence General Correspondence

NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC

01-Oct-2001 GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment

Response to FDA Request/Comment: CMC

04-Oct-2001 GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC General Correspondence

04-Oct-2001 Comment/Information Request: Clinical Food and Drug Administration Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request Clinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules Amendment to Pending Application: CMC

09-Oct-2001

GlaxoSmithKline Correspondence

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Serial / Supp #

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Amendment to Pending Application

30-Nov-2001 **Application:** 09-Oct-2001 09-Oct-2001 Date Range: 11-Oct-2001 JLP41868 10-Oct-2001 All NDA Food and Drug Administration Correspondence Food and Drug Administration Telephone Communication Type GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Minutes of Meeting: FDA Conference NDA 21-319; Dutasteride Soft-Gelatin Capsules Minutes of September 25 CMC Meeting General Teleconference: Meeting Request NDA 21-319; Dutasteride Soft-Gelatin Capsules Conversation Food and Drug Administration Correspondence 21319; Dutasteride Soft-Gelatin Capsules Minutes of Meeting Comment/Information Request General Teleconference Minutes of Meeting **Document Type** Amendment to Pending Application Chronology CMC Meeting Agenda or Details Meeting Request FDA Conference FDA Conference **Document Subtype** Serial / Supp # 12:17:58

NDA 21-319; Dutasteride Soft-Gelatin Capsules Amendment to Pending Application: CMC

30-Nov-2001 **Application:** NDA 21319; Dutasteride Soft-Gelatin Capsules Chronology

Date Range: ΑII

JLP41868

11-Oct-2001

GlaxoSmithKline Correspondence

Communication Type Document Type

General Correspondence

NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC Field Copy

11-Oct-2001 GlaxoSmithKline Telephone Conversation General Teleconference

NDA 21-319; Dutasteride Soft-Gelatin Capsules

General Teleconference: Clinical, Nonclinical, Safety

GlaxoSmithKline Correspondence General Correspondence

15-Oct-2001

NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: Other, Trade Name

15-Oct-2001 GlaxoSmithKline Telephone Conversation

Response to FDA Request/Comment

Clinical Pharmacology and Biopharmaceutics Review Letter Response to FDA Request/Comment NDA 21-319; Dutasteride Soft-Gelatin Capsules

Document Subtype

Serial / Supp #

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CMC Field Copy

Clinical Nonclinical

Safety

Labeling Other

Advisory Committee Meeting

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Communication Type

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17-Oct-2001 Food and Drug Administration Correspondence

Minutes of Meeting

FDA Conference

Minutes of Meeting: FDA Conference NDA 21-319; Dutasteride Soft-Gelatin Capsules

18-Oct-2001 GlaxoSmithKline Correspondence

General Correspondence

Other

NDA 21-319; Dutasteride Soft-Gelatin Capsules NDA 20-241; LAMICTAL® (lamotrigine) Tablets

General Correspondence: Request for a User Fee Refund Check

24-Oct-2001

GlaxoSmithKline Correspondence

Response to FDA Request/Comment

CMC

NDA 21-319; Dutasteride Soft-Gelatin Capsules

Response to FDA Request/Comment: CMC

24-Oct-2001

Food and Drug Administration Correspondence

Comment/Information Request

Labeling

NDA 21-319; Dutasteride Soft-Gelatin Capsules

Comment/Information Request: Labeling

31-Oct-2001 GlaxoSmithKline Correspondence

Response to FDA Request/Comment

Clinical BA/BE

Application: 30-Nov-2001 NDA

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Date Range: All

Communication Type

Document Type

Nonclinical

Document Subtype

21319; Dutasteride Soft-Gelatin Capsules

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Response to FDA Request/Comment

NDA 21-319; Dutasteride Soft-Gelatin Capsules

02-Nov-2001 GlaxoSmithKline FAX/E-mail

NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Labeling

Response to FDA Request/Comment

Labeling

GlaxoSmithKline Correspondence

Response to FDA Request/Comment

Labeling

05-Nov-2001

NDA 21-319; Dutasteride Soft-Gelatin Capsules

Response to FDA Request/Comment: Labeling

07-Nov-2001 Food and Drug Administration Correspondence

Comment/Information Request User Fee Invoice

NDA 21-319; Dutasteride Soft-Gelatin Capsules NDA 20-241; LAMICTAL® (lamotrigine) Tablet Re: GlaxoSmithKline, Request for Refund of Application Fees User fee ID #4203 and #4204

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30-Nov-2001 **Application:** NDA

21319; Dutasteride Soft-Gelatin Capsules

Chronology

Date Range: Date ΑII

08-Nov-2001 'GlaxoSmithKline Correspondence Communication Type

Document Type

Response to FDA Request/Comment

Document Subtype

Labeling

Serial / Supp #

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NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Labeling

08-Nov-2001 Food and Drug Administration FAX/E-mail

Comment/Information Request

Labeling

NDA 21-319; Dutasteride Soft-Gelatin Capsules

Comment/Information Request: Labeling

08-Nov-2001 GlaxoSmithKline Correspondence

Response to FDA Request/Comment

Labeling

NDA 21-319; Dutasteride Soft-Gelatin Capsules

Response to FDA Request/Comment: Labeling, Packaging

13-Nov-2001 Food and Drug Administration FAX/E-mail

Comment/Information Request

Labeling

NDA 21-319; Dutasteride Soft-Gelatin Capsules

Comment/Information Request: Labeling

15-Nov-2001 GlaxoSmithKline Correspondence

Response to FDA Request/Comment

Nonclinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules
Response to FDA Request/Comment: Nonclinical; Phase 4 Comittment

30-Nov-2001 Application: Date Range: NDA 21319; Dutasteride Soft-Gelatin Capsules Chronology

JLP41868

16-Nov-2001 GlaxoSmithKline Correspondence Communication Type Response to FDA Request/Comment Document Type

Labeling

Document Subtype

Serial / Supp #

Response to FDA Request/Comment: Labeling NDA 21-319; Dutasteride Soft-Gelatin Capsules

16-Nov-2001 Food and Drug Administration FAX/E-mail Comment/Information Request Labeling

NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Labeling

19-Nov-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment

Labeling

Response to FDA Request/Comment: Labeling NDA 21-319; Dutasteride Soft-Gelatin Capsules

20-Nov-2001 Food and Drug Administration Correspondence Approval Letter Labeling

NDA 21-319; Dutasteride Soft-Gelatin Capsules Approval Letter

30-Nov-2001 GlaxoSmithKline Correspondence

General Correspondence

General Correspondence: Other Notification of Corporation Name Change - Reproductive and Urologic

12:17:58

22 30-Nov-2001 **Application:** NDA

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Date Range: All Date C

Communication Type

Document Type

Chronology

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